Remington Medical, Inc.

MAY 1 3 2013



## 510(k) Summary

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| **Preparation Date** | March 4, 2013 |
| **Applicant** | Remington Medical, Inc.<br>6830 Meadowridge Court,<br>Alpharetta, GA, USA 30005<br><br>Registration Number: 1056553<br>Owner/Operator Number: 9006473 |
| **Contact Person** | Caitlin Senter, MS, RAC<br>Regulatory Affairs Manager<br>770-888-8520, extension 207<br>caitlins@remmed.com |
| **Trade Proprietary Name(s)** | Remington Medical CentreFire 22 Biopsy Instrument |
| **Common Name (s)** | Biopsy Instrument |
| **Classification Name** | 21 CFR 876.1075 (Instrument, Biopsy); Product Code: KNW |
| **Device Class:** | Class II |

**Legally Marketed Device to Which Substantial Equivalence is Claimed:**

Medical Device Technologies, Inc. Ultra (K962969)

**Description of the Device:**

The Remington Medical (RMI) CentreFire 22 Biopsy Instrument is a semi-automatic, reusable, spring-loaded mechanical device that is designed to be used with Remington Medical NAC Biopsy Needles to obtain core biopsy samples from the prostate.

**Intended Use/Indications for Use**

The Remington Medical CentreFire 22 Biopsy Instrument is used to obtain multiple core samples from the prostate. It is not intended for bone.

## Technological Characteristics:

The technological characteristics (design, specifications, and performance) of the subject device and the predicate device are substantially equivalent.

| | **Subject Device: Remington Medical CentreFire 22 Biopsy Instrument** | **Predicate Device: Medical Device Technologies Ultra, a.k.a. MANAN PRO-MAG™ ULTRA (K962969)** |
|---|---|---|
| Device Class<br><br>FDA Product Code<br><br>Regulation | Class II<br><br>KNW<br><br>21 CFR 876.1075 (Instrument, Biopsy) | Class II<br><br>KNW<br><br>21 CFR 876.1075 (Instrument, Biopsy) |
| Indications for Use Statement | The Remington Medical CentreFire 22 Biopsy Instrument is used to obtain multiple core samples from the prostate. It is not intended for bone. | The Ultra™ Biopsy Device is used to obtain multiple core samples from soft tissue such as the liver, kidney, prostate, breast, and various soft tissue lesions. It is not intended for bone. |
| Configuration | Reusable Biopsy Instrument for use with disposable biopsy needle assembly | Reusable Biopsy Instrument for use with disposable biopsy needle assembly |
| Needle Mounting Method / Compatible Needles | Proximal and Distal Carriages grooved to allow insertion of Biopsy Needles | Proximal and Distal Carriages grooved to allow insertion of Biopsy Needles |
| Cocking Method | Two-handed sequential operation | Two-handed sequential operation |
| Needle Sled (Carriage) Material | Plastic with stainless steel pins | Plastic with stainless steel pins |
| Needle Sled (Carriage) Propulsion | Stainless steel spring, one per sled/carriage | Stainless steel spring, one per sled |
| Cocked Sled (Carriage) Retention Method | Mechanical latch mechanism in instrument (Distal and Proximal) | Mechanical latch mechanism in instrument |
| Body Material | Aluminum (anodized) | Aluminum (anodized) |
| Guards/Safety | Automatic Safety | Automatic Safety |
| Reprocessing Method(s) | Manual Cleaning<br>Gravity Displacement Steam Sterilization (Autoclave) | Manual Cleaning<br>Gravity Displacement Steam Sterilization (Autoclave)* |

*Additional reprocessing methods were provided in the IFU for the predicate device but were not included in the subject device IFU

## Performance Data:

The Remington Medical CentreFire 22 Biopsy Instrument was evaluated in the following nonclinical performance studies: Needle Excursion (Penetration Depth) and Biopsy Sampling (Quality/Consistency).

Results of the performance testing demonstrates that the materials chosen, the manufacturing process and the design of the Remington Medical CentreFire 22 Biopsy Instrument meet the established requirements necessary for consistent performance during its intended use. The performance data also demonstrates that the Remington Medical CentreFire 22 Biopsy Instrument performs equivalent to the predicate device.

Reuse/Reprocessing validations were performed on the Remington Medical CentreFire 22 Biopsy Instrument to ensure appropriate cleaning and sterilization methods for the end user.

Results of the reuse/reprocessing validations demonstrates that the Remington Medical CentreFire 22 Biopsy Instrument meets the established requirements necessary for consistent reprocessing.

**Clinical testing:**

No clinical testing was required.

**Conclusion:**

The results of the non-clinical testing demonstrated that the subject device, Remington Medical CentreFire 22 Biopsy Instrument, is substantially equivalent to the predicate device, Medical Device Technologies, Inc. Ultra, with respect to intended use, materials, design, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

Remington Medical, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K130282
Trade/Device Name: Remington Medical CentreFire 22 Biopsy Instrument
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: May 1, 2013
Received: May 7, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Remington Medical, Inc.

# Indications for Use

510(k) Number (if known): K130282

Device Name: Remington Medical CentreFire 22 Biopsy Instrument

**Indications for Use:**

The Remington Medical CentreFire 22 Biopsy Instrument is used to obtain multiple core samples from the prostate. It is not intended for bone.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

**(Division Sign-Off)**
**Division of Reproductive, Gastro-Renal, and Urological Devices**
**510(k) Number** K130282